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13. ABSTRACT (Maximum 200 words) The aim of this study was to evaluate the performance of a unique ambulatory system when used with physically active individuals. Seven physically active male volunteers were monitored on three different periods under varying exercise conditions. The monitoring sessions were approximately 18 hours in duration and consisted of no activity, sedentary activity and vigorous exercise. After the monitoring sessions the system was downloaded and signal performance was analyzed for electrocardiogram (ECG), respiration rate (RESP), and blood oxygen saturation (SpO2). The results showed that signals performance, across all activity levels and sensor types was able to provide an acceptable signal 84% of the time (ECG = 96.9±3.0%, RESP = 71.2±13.1% and SpO2 = 83.7±13.8%). With the exception of the RESP signal, this instrument demonstrated that it could reliably provide the same accuracy in active persons as it does in sedentary persons.			
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**PERFORMANCE OF AN AMBULATORY CARDIORESPIRATORY
MONITORING SYSTEM DURING REST AND EXERCISE**

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The investigators have adhered to the policies for protection of human subjects as prescribed in Army Regulation 70-25, and the research was conducted in adherence with the provisions of 45 CFR Part 46.

Human subjects participated in these studies after giving their free and informed voluntary consent. Investigators adhered to AR 70-25 and USAMRMC Regulation 70-25 on the use of volunteers in research.

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EXECUTIVE SUMMARY

This study evaluated the reliability of a unique ambulatory monitoring system when used with physically active individuals. This monitoring system, manufactured by Nexan Incorporated (Nexan, Inc., Atlanta, GA; Nexan, Ltd., Cambridge, UK), measures and records full-disclosure electrocardiogram (ECG), respiration rate (RESP), and blood oxygen saturation (SpO2) data using a thoracic, multi-parameter, adhesive sensor array. This system was originally designed for home assessment of sleep apneas in sedentary outpatients. The purpose of the present study, which was part of a larger study, was to determine if this system could also reliably detect signals of ECG, RESP, and SpO2 in physically active individuals where motion, muscle activity, and lead detachment can degrade data quality.

Seven physically active male volunteers (age: 25 ± 5 y; ht: 179 ± 9 cm, wt: 76.4 ± 9.04 kg; body fat: $7.6 \pm 1.8\%$; VO_{2max} : 55.8 ± 9.2 ml•kg⁻¹•min⁻¹) were studied at 4300 m elevation at Pikes Peak, CO. Physiological monitoring was conducted over three periods of about 18 h each during the 14-day study period. During the first session (Days 1 to 2), the test volunteers were encouraged to participate in low to moderate activity, but generally were sedentary and physically inactive. The second session (Days 7 to 8) involved exercise that was moderate to vigorous in intensity, such as hiking, walking, running, cycle ergometer, basketball, jump roping, and weight lifting. In the third session (Days 13 to 14), subjects were asked to minimize physical activity for the entire period. The raw data files from the monitoring sessions were analyzed for signal acceptability; no attempt was made to determine the physiological accuracy of data collected. Data quality was expressed as the percentage of total recorded time with uncorrupted data.

The ECG, RESP, and SpO2 signals were analyzed for reliability and quality during varying levels of activity and day-to-day sessions. ECG and SpO2 signal quality were not affected by level of activity, but RESP signal quality showed a significant degradation with increasing activity level ($P < 0.05$). There was not a significant difference between the day-to-day comparisons of signal performance or quality.

Results showed, the Nexan System, across all levels of activity and sensor types, was able to provide an acceptable signal about 84% of the time (ECG = $96.9 \pm 3.0\%$, RESP = $71.2 \pm 13.1\%$, and SpO2 = $83.7 \pm 13.8\%$). With the exception of the RESP signal, this instrument demonstrated that it could reliably provide the same accuracy in active persons as it does in sedentary persons. The Nexan System should be used with a mesh T-shirt in order to keep electrodes from being snagged or pulled off during physical activity. This will reduce the occurrence of data dropouts from electrode movement or detachment. The routing of the lower left electrodes should be changed to reduce chaffing, and the connector between the SpO2 sensor and the Sender/radio module needs to be more robust.

INTRODUCTION

Continuous noninvasive ambulatory monitoring provides the ability to track normal and abnormal physiological changes that occur over extended periods. Compared to standard “spot” measurements, ambulatory monitoring offers a more comprehensive view of changes to the cardiorespiratory system (11), and can provide prognostic information that is usually only available in a clinical or laboratory setting (9,10). Ambulatory physiological monitoring can also be used to track thermal or high altitude acclimation state, or to assess the effectiveness of aerobic training.

Despite the advantages of ambulatory monitoring, challenges still arise: signal recognition in the presence of artifact (e.g., from muscle activity and postural changes), instrumentation size, poor durability, and excessive power requirements. Moreover, there may be problems maintaining sensor-subject contact because of anthropometric size (3). For example, adhesives may fail, thereby increasing the likelihood of data loss and artifact, and skin irritation can cause subject distress. In addition, motion and physical exercise can cause interference, especially if the activity is prolonged. Further, the hardware and/or software and algorithms in monitoring systems intended for use with sedentary and/or diseased populations may be poorly suited for gathering physiological data from physically active subjects.

The aim of the present study was to evaluate the performance of a unique ambulatory physiological monitoring system (Nexan, Inc., Atlanta, GA; Nexan, Ltd., Cambridge, UK). The Nexan system, originally designed for sleep studies, continuously records electrocardiogram (ECG), respiratory rate (RESP), and blood-oxygen saturation (SpO₂) using a thoracic, multi-parameter, adhesive sensor array. A key goal was to assess the performance of this system when used with physically active people.

METHODS

TEST VOLUNTEERS

This study was part of a larger U.S. Army Research Institute of Environmental Medicine (USARIEM) study entitled “Effect of increased energy expenditure, antioxidant intervention, and carbohydrate ingestion on work performance and acclimatization to 4,300 m altitude.” Data were collected from 18 test volunteers (age: 25 ± 5 y; ht: 179 ± 8.2 cm; wt: 77.7 ± 8.2 kg; body fat: $8.4 \pm 3.3\%$; VO_{2max} : 55.8 ± 6.8 ml•kg⁻¹•min⁻¹). Data are presented for the seven volunteers (age: 25 ± 5 y; ht: 179 ± 9 cm; wt: 76.4 ± 9.04 kg; body fat: $7.6 \pm 1.8\%$; VO_{2max} : 55.8 ± 9.2 ml•kg⁻¹•min⁻¹) who completed all three days of ambulatory monitoring with all three levels of activity. All volunteers were physically fit, healthy, non-smoking males with no history of heart disease or asthma.

ENVIRONMENTAL CONDITIONS

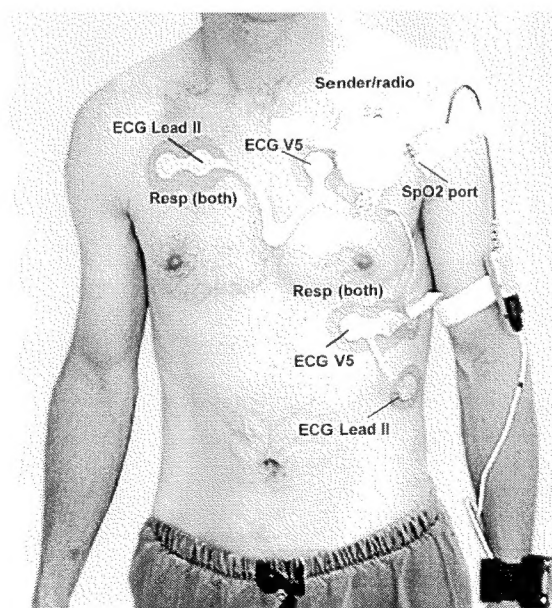
All outside activity was between 4,300 m and 3,366 m elevation, with environmental conditions of $17.7 \pm 5^{\circ}\text{C}$ air temperature, with a $31 \pm 4\%$ relative humidity.

INSTRUMENTATION

The ambulatory Nexan System (Nexan, Inc., Atlanta, GA; Nexan, Ltd, Cambridge, UK) was developed with engineering assistance provided by Hidalgo, Ltd, Cambridge UK (www.hidalgo.co.uk). It was designed for the collection and post-hoc analyses of ECG, RESP, and SpO2 data from outpatients suspected of having sleep apnea and other related disorders. The device is worn on the upper torso to collect cardiopulmonary measurements. It has three major parts (Figure 1): Part 1, a sensor patch--a disposable, multi-parameter adhesive electrode assembly worn on the upper chest. The low-profile sensor assembly has an array of six adhesive electrodes connected by flat, non-adhesive leads to a connector containing two AAA batteries. The ECG pickups are arranged to provide a modified lead 2 and a modified CMV5 view of the heart. Respiration rate is measured by a one-channel bioelectric impedance method using four electrodes made up of both drive and sense electrodes. The Nexan System also gathers SpO2 data using a Nonin model 700A Pulse Oximeter Sensor that is typically attached to the left index finger and connects to the Sender through a dedicated socket. Part 2, the "Sender/radio"--a radio frequency data transmission unit that is clipped on to the sensor patch. The Sender clip is powered by the 2 AAA batteries in the sensor patch. Part 3, A PDA receiver (not seen in figure 1.) -- the receiver is a body-worn, PDA receiver that receives and stores the data from the Sender unit. Once the data is stored it has to be downloaded to a personal computer for post-hoc analysis.

Electrocardiogram (ECG) data are collected at 250 samples per second, RESP data are collected at 25 samples per second, and SpO2 data are collected once every 0.4 second.

Figure 1. The Nexan system configuration



EXPERIMENTAL APPROACH

Before attaching the electrode assembly to the test volunteer, chest hair was shaved and the skin was cleaned with an isopropyl alcohol swab. The electrode assemblies came in four sizes--small, medium, large, extra large--that were fitted to the subjects. Once the system was attached to the test volunteer and the Sender unit clipped onto the electrode assembly, the wireless transmission of data to the belt-mounted PDA logger commenced.

Because movement has been well documented to affect accuracy of surface sensors (1, 8), all subjects wore a stretchable mesh t-shirt to help secure electrodes for extended use. This helped reduce lead movement and motion artifacts. There was no skin irritation associated with the adhesive electrodes noticed during this study. Adhesion did not seem to be compromised during extended use, nor was it affected by exercise, although electrodes could shift during profuse sweating. This electrode movement was minimal, and reapplication of the sensor patch was not necessary.

Ambulatory monitoring data were collected during three, 18-h periods over the course of 14 days at 4300 m elevation (Pikes Peak, CO). The mean time that the Nexan device was attached to the subjects over the 3 days of ambulatory monitoring was 18.21 ± 2.64 h. The first monitoring session (Days 1 to 2) began late afternoon and involved sedentary activity and no activity (sleep). The session was completed upon awakening the following morning. The second session (Days 7 to 8) started at morning awakening and involved moderate to vigorous exercise such as hiking, walking, running, cycle ergometer, basketball, jump roping, and weight lifting. Monitoring continued throughout the sedentary evening activity until the morning awakening when monitoring was completed. The third session (Days 13 to 14) followed the same timeline as the second session but required no exercise; subjects were asked to remain sedentary for the entire monitoring period. At the end of the data collection periods, on awakening, each test volunteer usually removed his own Nexan device. After removal of the devices, the scientific staff promptly downloaded and stored the files for later analysis.

DATA ANALYSIS

Raw data were analyzed for signal disturbances, including artifacts, outliers, missing data, or excessive noise that made the signal unavailable or un-interpretable. The total duration of unacceptable data was subtracted from the total period of data collection and a percentage of acceptable data were calculated.

Specifically, ECG tracings were analyzed for R-waves. The R-wave was chosen because of its distinct shape and the fact that it tends to be obvious among artifacts caused by muscle tremors, movement of electrode leads, and baseline deflections. Data were divided into two groups: acceptable data that showed clear R-R intervals, and unacceptable data that were missing or of poor quality with irregular R-R patterns. Normal physiologic bounds were used in the analysis of the data; R-to-R intervals of

less than 0.28 seconds or exceeding intervals of 2.0 seconds were considered outliers and dropped from the analysis.

The impedance signal, used to estimate respiratory rate (RESP), was sampled 25 times per second. The total duration of unacceptable RESP data were subtracted from the total data collection period to calculate a percentage of acceptable data. Because impedance patterns are variable and specific to each individual (that is, there are no normal bounds to apply), unacceptable data were defined as periods of missing data or corrupted data.

SpO2 data, expressed as a percentage of oxygen saturation of arterial blood, were recorded every 0.4 sec, and post-hoc analysis was performed after averaging 8 sec of data. Values of zero (no signal) or less than 50% were considered outliers. Reference data suggest that SpO2 should range from 55%-75% during maximal exercise at 5400 m (2). The accuracy of the Nonin model 700A has only been tested between 70%-100% saturation (± 1 standard deviation). Barthelemy et al. (1) found that pulse oximeter saturation values above 75% were most reliable during low intensity exercise.

To determine the functionality of the Nexan system, the recorded signals from ECG, RESP, and SpO2 were analyzed for performance. Performance was ascertained for each signal type. Comparisons were carried out on activity type and day-to-day performances. This made it possible to determine the reliability of each device. Once reliability could be established, performance vulnerabilities could be evaluated. Results are presented as total recorded time divided by total artifact time. In order to normalize data, percentages were used to illustrate differences in recorded times and performance quality. Data were analyzed using a two-way analysis of variance (ANOVA) with repeated measures and a 0.05 level of significance. Data are reported as mean \pm SD.

In order to make conditional comparisons to sensor performance work intensities were determined by self recorded physical activity logs. Activity logs were kept throughout duration of the study and subjects were urged to complete them as often as possible. Because activities varied significantly, 3 classifications were made to simplify the intensities (table 1).

Table 1. Definition of Activity Types.

Activity Class	Activity	Work Intensity	MET Level
No activity	Sleeping, lying down.	Very Light	0.8 -1 MET
Sedentary	Sitting, walking slow, standing, talking.	Light	1.1 to 3.0 METs
Exercise	E.g., Marching, stationary biking, jump roping, basketball.	Moderate to Vigorous	3.1 to 16+ METs

* Reformatted from USARIEM TECHNICAL NOTE 93-1 December 1992. 1 MET = 105 watts

RESULTS

The performance of the individual sensors showed a mean decline in signal attainability to increasing activity levels, but there was no significant difference found in signal attainability for ECG or Spo2. Performance of the ECG sensor is shown in table 2. The recorded signals were divided into three categories according to activity level, and it was shown that activity level had no significant affect on ECG performance.

Table 2. Electrocardiogram (ECG) sensor performance expressed as a percent of uncorrupted data during three levels of activity.

	No activity	Sedentary activities	Exercise
Mean ^a	98.7	97.1	94.9
SD	2.2	2.0	4.8

^a There was no statistical difference between the different levels of activity.

The only signal that was directly affected by activity level was the RESP signal. Table 3 shows the differences in RESP signal attainability for each activity level. The RESP signal performance was shown to be affected by activity type which lead to the 27.2% decline in signal attainability during sedentary activities. The statistical difference in respiratory rate data quality is seen during sedentary activity and physical activity. However, once signal attainability dropped, it remained about the same during sedentary activity and exercise.

Table 3. Respiration rate (RESP) sensor performance during three different levels of activity, shown as a percentage of uncorrupted data.

	No activity	Sedentary activities	Exercise
Mean ^b	87.5*†	60.3*	65.8†
SD	8.8	17.6	12.7

*Significant difference between no activity and sedentary ($P<0.05$).

†Significant difference between no activity and exercise ($P<0.05$).

Performance of the SpO2 signal can be seen in table 4. It was shown that signal performance was not significantly affected by activity type. Although there was a slight decline in the mean SpO2 values during exercise by 7.8% no significant affect was found.

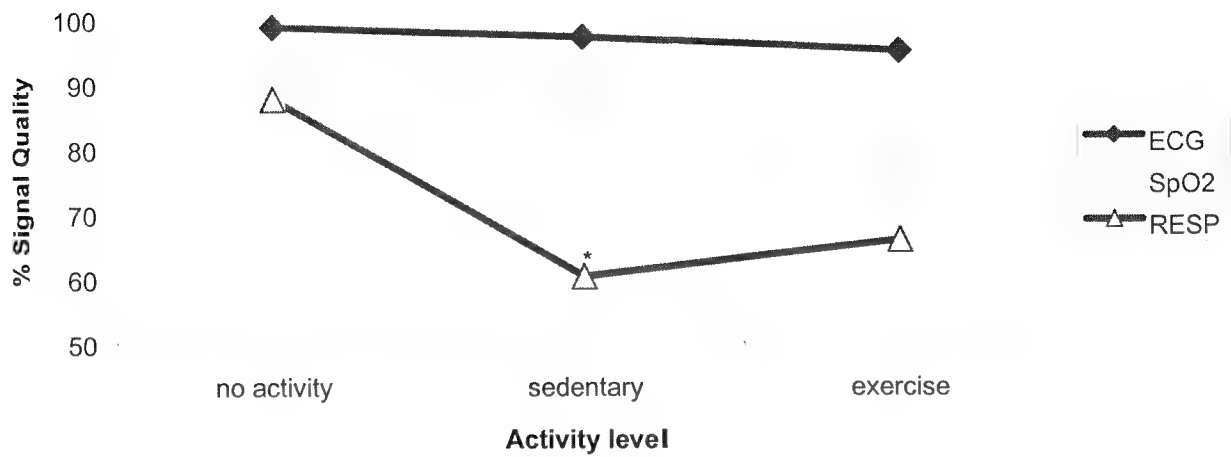
Table 4. Pulse oximeter (SpO2) sensor performance during three different levels of activity shown as a percentage of uncorrupted signal data.

	No activity	Sedentary	Exercise
Mean ^c	87.1	85.9	78.1
SD	18.9	7.5	15.4

^c No statistical difference was evident between the different levels of activity.

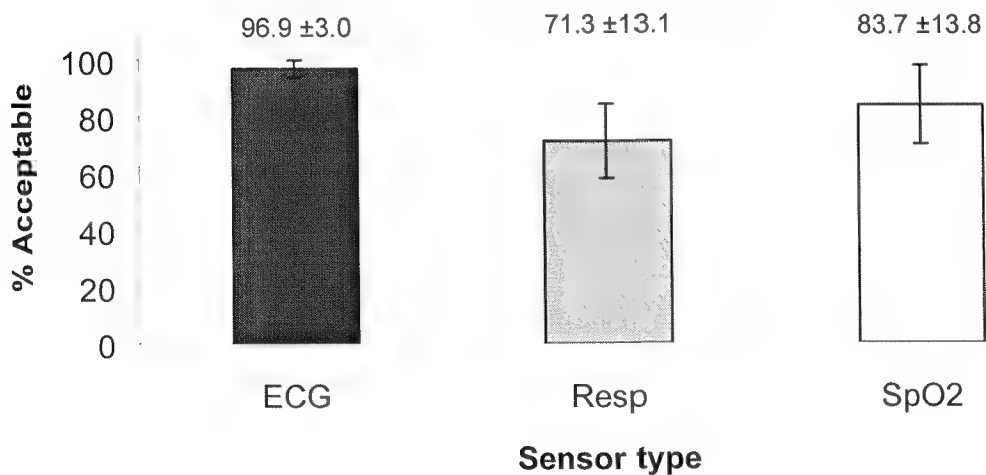
Figure 2 shows the performance and variability in performance for the three sensors during different levels of activity expressed as a percentage of acceptable data. The asterisk (*) indicates a significant difference between RESP and sedentary ECG and SpO2 data under sedentary conditions. The differences in RESP signal attenuation may be caused by body positioning more than the activity itself. This decline was the only significant effect to the level of activity.

Figure 2. Sensor performance as a function of activity level



Overall system performance across all levels of activity and all test days can be seen in figure 3. This graph depicts the mean operational score for acceptable signals.

Figure 3. Overall system performance for the ECG, respiratory rate, and SpO2 sensors



Data were presented for 7 of the 18 test volunteers who completed all 3 days of ambulatory monitoring and fulfilled the three modalities of activity (no activity, sedentary, and exercise). There were no significant day-to-day differences in sensor performance for the three data types: ECG, RESP, and SpO2.

DISCUSSION AND CONCLUSIONS

Our investigation demonstrated that the Nexan ambulatory monitoring system was able to reliably collect ECG, RESP, and SpO₂ signals from physically active males. With the employment of a form-fitting mesh t-shirt; good electrode contact was maintained. Also, the low profile electrodes made a form-fitting assembly that was not protrusive and allowed unrestricted movement. Even though the device was originally designed for sedentary outpatients, it was able to provide the same reliability and signal attainability on active participants.

The findings from our study demonstrated that the ECG arrangement repeatedly and reliably provided signals of cardiac frequency during all of the modes of activity. It also should be noted that activity type had no significant effect on signal attainability. Since activity had no significant effect signal acceptance was 96.9% throughout the study's duration. These findings also coincide with the findings from Johnson et al. and his prototype Nexan system (3).

The significant outcome of our study showed that there was a difference in signal attainability of RESP performance during the transition from no activity to sedentary activity. The decline in signal quality remained about the same during both sedentary and exercise bouts. Even though the performance declined during sedentary and exercise periods, relatively good quality data were obtained during no activity. The differences in signal attainability can be expanded by anatomical and mechanical factors.

The majority of the disturbances can be attributed to electromyogram (EMG) artifact associated with the motion of the thorax. Impedance is affected with an increase in movement and changes to body positioning (12). Also, during no activity bouts, subjects were mostly sleeping or in the supine position. During these periods, movements were reduced and breathing mechanisms changed causing less obstruction to the signals. It has been shown that during sleep there is a decreased drive to the upper airway muscles (4). This decrease in drive causes an increase in resistance, which may have caused more forceful and deeper inspirations leading to more distinct measurements (7). These changes may have further improved signal attainability. Also, because plethysmographic measurement accuracy depends on the immobility of the subject (8), data would be most reliable during the no activity periods.

The mechanical factors that contributed to the signal degradation were caused by lead disconnection due to the design of the respiratory electrode configuration. Detachment of the lower left electrode in the left supra-iliac position tended to occur because of a dramatic bend in the flat lead leading to this particular electrode and because of inadequate electrode adhesion (indicated by the arrow in Figure 4). This abrupt bend caused pulling of the attachment point and often disrupted the RESP signal. Many of the adhesion problems inherent at this specific electrode still occurred when a mesh T-shirt was used (see Figure 4).

Figure 4. View of mesh t-shirt and configuration of lower left ECG electrodes. The arrow indicates the bend in the electrode on the left supra iliac position.



The SpO2 performance was statistically unaffected by activity type. The decline in oximetry (SpO2) performance can mostly be attributed to movement artifacts. During activity, movement of the sensor attached to the finger may have changed the volume of tissue being interrogated by the optical sensor, disrupting determinations of SpO2. Furthermore, the mini-stereo plug between the oximetry sensor and the Sender unit were not secure and tended to pull out. There is also a point where the SpO2 sensor wire connects to the mini-stereo jack that is also prone to disconnection. The problems due to wire disconnection at the mini-stereo jack port were partially resolved by strain-relieving and securing the mini-stereo plug to the Sender unit with tape. However, disconnection still occurred causing dropped rather than erroneous values.

The signal processing/data transmission unit (Sender) tended to move with the chest and caused friction with the overlying clothing, putting the electrode array under tension. The friction between Sender and clothing, over time, would cause the chest electrodes to migrate and pull off in some instances. This lead movement may have introduced artifact into the data. With this in mind, signal quality could be improved with the relocation of the Sender transmitter unit. Also, the placement of the Sender unit conflicted with the shoulder straps on backpacks, causing discomfort.

In conclusion, across all levels of activity and across all sensor types, the Nexan System, when used with a stretchable mesh T-shirt, provided acceptable data 84% of the time (HR = $96.9 \pm 3.0\%$, RESP = $71.2 \pm 13.1\%$, and SpO2 = $83.7 \pm 13.8\%$ acceptable). This coincides with the findings from Johnson et al. (5) and their Nexan prototype with ECG performance attainable for 98% of the recording time and RESP at 74%. Although Johnson et al. did not measure SpO2 and used a subject pool of elderly patients, ECG and RESP were similar. This can be explained by the findings of this study, that exercise had no significant effect on ECG signal quality attainability. For RESP data, the findings did not compare activity type to signal quality, but the overall performances were within 4%. Also, a more recent study from de Lusignan (3) demonstrated

improved signal acceptability for cardiac frequency and respiration rate, but the duration was substantially shortened by 16-22 h. Therefore, our results fall within the ranges set from previous studies, and application error did not come into effect. Although it was not clear in the report from Johnson et al. how the prototype and the “newer” Nexan devices differ, it is clear that the performance levels remained constant between both investigations.

Thus, this instrument seems to be an adequate device for collection of physiological data from physically active healthy male population, although respiratory rate detection was affected by activity. It was also demonstrated that a thoracic sensor node containing multiple sensor types could function effectively. The straightforward configuration is noninvasive and generally user-friendly. However, there are some durability issues related to the sensor electrodes for RESP and the remote sensor used for SpO₂ measurements. Otherwise, electrode adhesion appeared adequate.

COMMENTS AND RECOMMENDATIONS

- It was possible to reliably collect ECG data from physically active individuals using adhesive electrodes.
- The flat, breathable adhesive electrode assembly was unobtrusive, allowing freedom of movement, and was not associated with skin irritation.
- The approach of having multiple sensors at a single site or node appeared effective.
- The shape and position of the data processing/telemetry unit (Sender) should be modified to make it more comfortable, less likely to interfere with pack straps, and less likely to put the adhesive electrodes under tension.
- The oximetry sensor attached to the finger was obtrusive, and the wire connecting it to the Sender telemetry unit was prone to breakage and disconnections.
- Physiologic data were successfully collected from physically active individuals using a wearable system that incorporated flat, breathable, adhesive electrodes. Although non-adhesive sensing is likely to be part of the ultimate solution, the success of this approach suggests it deserves further study.
- Further development of a wearable wireless physiological monitor can increase the ability of using prognostic information in field applications that can assist in casualty care, increasing the possibility of survival/treatment considered for medical intervention/early identification.
- Ambulatory monitoring has the ability to medically ascertain vital signs such as cardiac frequency, respiration frequency, and blood oxygen saturation percentage.

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